

PSJ10 Exh 12

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4

5 -----x
6 IN RE: NATIONAL PRESCRIPTION) Case No.
7 OPIATE LITIGATION) 1:17-MD-2804
8 APPLIES TO ALL CASES) Hon. Dan A. Polster
9 -----x

10
11 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12 CONFIDENTIALITY REVIEW
13 VIDEOTAPED DEPOSITION OF MICHAEL R. CLARKE

14 SANDSTON, VIRGINIA

15 FRIDAY, DECEMBER 7, 2018

16 9:13 A.M.
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24 Reported by: Leslie A. Todd

1 Deposition of MICHAEL R. CLARKE, held in the
2 conference room of the:

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HILTON GARDEN INN

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RICHMOND AIRPORT

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441 International Center Drive

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Sandston, Virginia 23150

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Pursuant to notice, before Leslie Anne Todd,

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Court Reporter and Notary Public in and for the

16

Commonwealth of Virginia, who officiated in

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administering the oath to the witness.

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1 A P P E A R A N C E S

2

3 ON BEHALF OF PLAINTIFFS:

4 MATTHEW S. MELAMED, ESQUIRE

5 KELLI BLACK, ESQUIRE

6 ROBBINS GELLER RUDMAN & DOWD LLP

7 Post Montgomery Center

8 One Montgomery Street

9 Suite 1800

10 San Francisco, California 94104

11 (415) 288-4545

12

13 ON BEHALF OF THE ALLERGAN DEFENDANTS AND THE

14 WITNESS:

15 JENNIFER G. LEVY, ESQUIRE

16 CATIE VENTURA, ESQUIRE

17 KIRKLAND & ELLIS LLP

18 655 Fifteenth Street, N.W.

19 Washington, D.C. 20005

20 (202) 879-5211

21

22

23

24

1 APPEARANCES (Continued):

2

3 ON BEHALF OF WATSON PHARMACEUTICALS, INC.:

4 STEVEN A. LUXTON, ESQUIRE

5 MORGAN LEWIS BOCKIUS, LLP

6 1111 Pennsylvania Ave, N.W.

7 Washington, D.C. 20004-2541

8 (202) 739-5452

9

10 ON BEHALF OF MCKESSON CORPORATION:

11 SARA SUNDERLAND, ESQUIRE (Telephonically)

12 COVINGTON & BURLING, LLP

13 One Front Street

14 San Francisco, California 94111-5356

15 (415) 591-6000

16

17 ON BEHALF OF ENDO PHARMACEUTICALS, INC. and

18 ENDO HEALTH SOLUTIONS, INC.:

19 JOHN CELLA, ESQUIRE (Telephonically)

20 JOANNA PERSIO, ESQUIRE (Telephonically)

21 ARNOLD & PORTER KAYE SCHOLER, LLP

22 601 Massachusetts Ave, N.W.

23 Washington, D.C. 20001-3743

24 (202) 942-5000

1 APPEARANCES (Continued):

2

3 ON BEHALF OF WALMART:

4 SHIRLETHIA V. FRANKLIN, ESQUIRE

5 JONES DAY

6 51 Louisiana Avenue, N.W.

7 Washington, D.C. 20001-2113

8 (202) 879-3939

9

10 ON BEHALF OF AMERISOURCEBERGEN:

11 JILL McINTYRE, ESQUIRE (Telephonically)

12 JACKSON KELLY, PLLC

13 500 Lee Street East

14 Suite 1600

15 Charleston, West Virginia 25301-3202

16 (304) 340-1018

17

18 ON BEHALF OF CARDINAL HEALTH:

19 JULI ANN LUND, ESQUIRE (Telephonically)

20 WILLIAMS & CONNOLLY LLP

21 725 Twelfth Street, N.W.

22 Washington, D.C. 20005

23 (202) 434-5000

24

1 APPEARANCES (Continued):

2

3 ON BEHALF OF MALLINCKRODT PHARMACEUTICALS:

4 PHILLIP KRAFT, ESQUIRE (Telephonically)

5 ROPES & GRAY, LLP

6 1211 Avenue of the Americas

7 New York, New York 10036-8704

8 (212) 596-9150

9

10 ALSO PRESENT:

11 CHRIS RITONA (Videographer)

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1 specifically.

2 Q Did it have anything to do with opioids?

3 A I don't believe that it did.

4 Q And then you left University of Medicine
5 and Dentistry to join Biomet Spine and Bone
6 Healing, correct?

7 A Yes.

8 Q And you -- at Biomet Spine and Bone
9 Healing, you were vice president and compliance
10 officer from June 2008 until approximately 2000 --
11 beginning of 2012; is that correct?

12 A Yes.

13 Q What was your primary responsibility as
14 vice president and compliance officer at Biomet?

15 A EBI, Biomet Bone Healing was the -- was
16 a division of Biomet, the orthopedics company, and
17 that division was located in New Jersey. My role
18 was to build out the compliance program for that
19 division of Biomet.

20 Q In that role at Biomet, did you address
21 any issues related to opioids?

22 A No. Biomet was an orthopedic device
23 company.

24 Q And after leaving Biomet, you joined

1 Actavis, correct?

2 A Yes.

3 Q And you were at Actavis for three and a
4 half years approximately; is that correct?

5 A I know I was at Actavis from early 2012
6 until the middle of 2015.

7 Q What was the name of the position you
8 held at Actavis? And if it was more than one, the
9 name of the positions.

10 A I believe the title remained the same.
11 I believe I was vice president of compliance for
12 the Americas or something like that.

13 Q And what were your responsibilities as
14 vice president of compliance for the Americas?

15 A My role at Actavis was again to build
16 out the compliance program for that division of
17 the company. Actis evolved -- Actavis evolved
18 over time into a different sort of company. So it
19 started off as a regional role for the Americas
20 and then became something else.

21 Q How did -- when you said "Actavis
22 evolved over time," what do you mean by that?

23 A Actavis was acquired by Watson, and then
24 the combined company acquired other companies

1 until the time I left.

2 Q And throughout the time that you were
3 there, you were working on compliance issues in
4 Actavis, and then Actavis was acquired by Watson,
5 and then in the subsequent companies as well where
6 there were acquisitions?

7 A Yes.

8 Q What department were you in at Actavis?

9 A I was in the compliance department.

10 Q And who was -- who did you report to in
11 the compliance department?

12 A When I first joined the company, I
13 reported to Kirsten Schmal (phonetic), who was
14 the, I believe, the chief compliance officer at
15 what I'll call Swiss Actavis, and he resided -- or
16 the company's headquarters was in Zug,
17 Switzerland -- for about a year.

18 And then after the Watson acquisition, I
19 reported to Deborah Penza, who was the compliance
20 officer resident at that point in the Parsippany
21 office, and I reported to Deb Penza until the
22 close of the Allergan acquisition, at which point
23 I still reported to Deb while she was there, but
24 then I had an indirect report to JK, John

1 Kellerman, who became the Allergan global
2 compliance officer.

3 Q Did Deb Penza work at Watson prior to
4 its acquisition of Actavis?

5 A Yes. Deb was the Watson compliance
6 officer.

7 Q Prior to the acquisition, were you the
8 highest ranking member of the compliance team in
9 the United States, if you know?

10 A Prior to the Watson acquisition?

11 Q Yes.

12 A I was the highest ranking member of the
13 compliance team at Actavis in the U.S. because I
14 was the only member of the compliance team at
15 Actavis in the U.S.

16 Q Do you know if prior to January 2012
17 when you started at Actavis whether there was a
18 compliance team for Actavis in the United States?

19 A There were people managing the
20 compliance function prior to me starting at
21 Actavis. It was managed by lawyers on the Actavis
22 team or different lawyers on the Actavis team, and
23 there was also a contract group at Adventive.
24 Well, Adventive was a contract sales organization,

1 and there was a compliance officer in Adventive
2 who managed compliance for the contract function
3 that supported Actavis at that time.

4 Q Who were the Actavis lawyers who managed
5 compliance before your arrival?

6 A John LaRocca and Beth Zelnick-Kaufman.

7 Q And who were the people at Adventive who
8 managed their compliance vis-à-vis their
9 relationship with Actavis?

10 A Scott Miller.

11 Q Were each of those individuals lawyers?

12 A John and Beth are lawyers. I don't know
13 if Scott is a lawyer or not.

14 Q You mentioned that you -- earlier that
15 you did not leave Actavis voluntarily; is that
16 correct?

17 A That's correct.

18 Q What are the circumstances under which
19 you left Actavis?

20 A With the Actavis-Allergan acquisition,
21 there was a reorganization of a number of
22 different business functions within the combined
23 company, and a number of commercial and financial
24 and other functions, some legal functions and the

1 compliance function were reorganized, and certain
2 people in each of those functions and others left
3 the company.

4 Q Were you asked to leave the company?

5 A Yeah. Yes.

6 Q Was that -- did that request have
7 anything to do with an evaluation of the quality
8 of your work?

9 A No. It had to do with business
10 operations, a reorganization of the company under
11 the Allergan -- after the Allergan combination,
12 and a desire that certain people in certain
13 functions were no longer needed, and hence, we
14 were reorganized out of the company.

15 Q Once -- while you were at Actavis and it
16 was acquired by Allergan, do you know the name of
17 the company you worked for?

18 A Well, the company --

19 Q I'm sorry. Let me -- I --

20 A Okay.

21 Q I jumped over a few steps there. Sorry
22 about that.

23 When you were at Actavis and it was
24 acquired by Watson, do you know the name of the

1 company you worked for after the acquisition?

2 A Yes.

3 Q And what was that?

4 A The company name remained Actavis.

5 Q And who -- what was the corporate entity
6 that employed you at that time after the Watson
7 acquisition?

8 A It was Actavis, I believe, after the
9 Watson -- excuse me, after the Watson acquisition,
10 it became Actavis PLC, because I believe Watson
11 was headquartered in the UK.

12 Q Prior to the acquisition, when you first
13 started at Actavis, what was the name of the
14 corporate entity that employed you?

15 A Well, before the Watson acquisition, we
16 were what I call Swiss Actavis, so I believe we
17 were Actavis, Inc., which was headquartered in
18 Switzerland. It might have even been incorporated
19 in Iceland. There was an Iceland connection and a
20 Switzerland connection, but it was based in
21 Central Europe.

22 Q And -- and then once Allergan came into
23 the picture and acquired Actavis, what was the
24 corporate entity you worked for prior to the time

1 you departed?

2 A I know the corporate name changed to
3 Allergan at some point. So it was still Actavis
4 after the deal closed, and it became Allergan at
5 some point. I think, as I was leaving, the
6 corporate name changed to Allergan. I don't know
7 if it was Inc. or PLC or anything else, but it
8 changed from Actavis to Allergan at some point in
9 the spring of 2015.

10 Q And then when you left Actavis, you,
11 after a couple of months, secured employment at
12 Indivior, correct?

13 A I left Actavis-Allergan in June of 2015.
14 I started working at Indivior in August of 2015.

15 Q And you still work at Indivior, correct?

16 A Yes, I do.

17 Q And what's your title at Indivior?

18 A My current title is vice president,
19 corporate compliance.

20 Q Has that been your title the entire time
21 you've been there?

22 A Yes.

23 Q And what's your responsibility?

24 A I -- up until the beginning of October,

1 I was the global compliance officer for Actavis --

2 I'm sorry, for Indivior.

3 Q I'll do the same.

4 A So I managed the global compliance
5 program for Indivior.

6 Q And then what happened in October?

7 A In October, the corporate compliance
8 function moved out of legal, because it sat within
9 the legal department, and it became its own
10 freestanding department, and we hired a chief
11 compliance officer who sits on our executive
12 management team, whom I now report to.

13 Q And are you in the legal department
14 currently at Indivior?

15 A No, I'm in the integrity and compliance
16 department at Indivior.

17 Q What is Indivior's business?

18 A Indivior is a specialty pharmaceutical
19 company.

20 Q Do they manufacture pharmaceuticals?

21 A Yes, we manufacture specialty
22 pharmaceuticals.

23 Q And sell those pharmaceuticals, correct?

24 A We distribute those pharmaceuticals,

1 for the manufacture and sale of certain drugs?

2 A Certain controlled drugs, yes.

3 Q Certain controlled drugs.

4 Do you recall the purpose of this
5 meeting?

6 Well, let's start out, do you recall who
7 requested this meeting? Whose idea was it?

8 A Well, the DEA requested the meeting.

9 Q Do you recall why they requested it? Do
10 you have an understanding of why?

11 A I don't know why they requested it
12 because I wasn't in those discussions. I just
13 know we received a request from the DEA to meet
14 with us. I guess someone scheduled it, it was set
15 up, and then the Actavis folks went down.

16 Q Other than the government side, the
17 individuals in different government agencies and
18 the individuals from Actavis, was there anybody
19 else in attendance at the meeting?

20 A I know -- I believe we had talked about
21 whether we should bring counsel, but -- if it
22 was -- I believe we did, I just don't remember
23 specifically, but we decided not to. I don't
24 think there was a need for it.

1 So on the Actavis side, it was just
2 internal Actavis folks, from what I remember. And
3 then, like I said, different divisions or
4 departments within the DEA, the enforcement folks
5 and then the quota folks.

6 Q It was just a bilateral meeting between,
7 generally speaking, the DEA side and the Actavis
8 side; is that correct?

9 A That's what I remember, yes.

10 Q Do you recall the purpose of the meeting
11 generally?

12 A I think as a general matter, it was a
13 meeting for -- ostensibly for the DEA to talk to
14 us about our anti-diversion efforts.

15 Q And you say "ostensibly." Why -- why do
16 you qualify it in that way?

17 A I qualify it that way based on how the
18 meeting went, the tone and the tenor of the
19 meeting, meaning that it was less productive than
20 it could have been, and it could have -- the
21 purpose to discuss anti-diversion efforts could
22 have been achieved in a different way, with a
23 different tone and a different type of
24 presentation, and looking and talking to us as --

1 who were on the manufacturing side, as
2 professionals as opposed to street dealers.

3 Q Am I correct -- reading between the
4 lines of your answer, am I correct that the DEA
5 was critical of Actavis's anti-diversion efforts
6 in that meeting?

7 MR. LUXTON: Objection.

8 THE WITNESS: I wouldn't put it that
9 way. I think -- the way I looked at it -- the
10 way -- and, you know, we talked afterwards. It
11 wasn't so much as just being critical of our
12 anti-diversion efforts. The undertone of the
13 meeting was an implicit criticism of the fact that
14 we were making these products in the first place,
15 and we were -- and when I say "we," I mean Actavis
16 was at that meeting, but they referred to one or
17 two other companies that were also making generic
18 opioid products as not being responsible. And in
19 a sense that they described it, without using
20 these specific words, but in a way that we would
21 just manufacture, put the product out on the
22 street, and not have a care as to where it went.

23 Because they described their efforts
24 at -- you know, whatever enforcement efforts they

1 were engaged in, they described finding or seeing
2 or obtaining product, you know, opioid products
3 that seemed to be diverted relatively easily, I
4 guess is the way to describe it.

5 So it was -- you know, and they were
6 haranguing us about certain things. So it just
7 was not the most productive conversation about
8 anti-diversion efforts, about manufacturing of
9 these products, things like that.

10 BY MR. MELAMED:

11 Q You mentioned that they mentioned -- the
12 DEA mentioned during this meeting one or two other
13 manufacturers of generic opioids, correct?

14 A Yes.

15 Q Do you recall who they -- who the DEA
16 mentioned?

17 A I know they mentioned more than one, but
18 Mallinckrodt was one name that came up that I
19 recall.

20 Q And you don't recall any other names?

21 A I don't remember at this point.

22 Q Do you see the sub-bullet point --
23 returning to Exhibit 4, the sub-bullet point that
24 says: "Discussion of likely diversion of

1 oxycodone in FL and other high risk states"?

2 A Yes.

3 Q FL stands for Florida, right?

4 A That's right.

5 Q Do you recall which other high risk
6 states were discussed?

7 A I believe -- I mean, the discussions
8 seemed to focus mostly on the East Coast. So it
9 was Florida, I remember that specifically, and
10 they spent most of the time on Florida, so the
11 other states were almost secondary, tertiary.
12 They might have mentioned Virginia or West
13 Virginia. I know they mentioned other states, but
14 I -- I would be guessing, and I don't want to do
15 that. I don't recall specifically.

16 Q Do you remember whether the DEA had
17 anything to say about Actavis's suspicious order
18 monitoring program during that meeting?

19 A Yeah, I mean, ultimately the discussion
20 came over to that because, you know, that's what
21 we were prepared -- the Actavis team was prepared
22 to talk about. And without knowing -- because I'm
23 not sure if there was an agenda, without knowing,
24 you know, a list we're going to, you know, talk --